IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant(s):	Edward W. MERRILL *et al.*	Confirmation No.: 8881
App. No.:	09/764,445	Examiner: S. Berman
Filing Date:	January 19, 2001	Group Art Unit: 1796
Title:	RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE PROSTHETIC DEVICES	

United States Patent and Trademark Office
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Alexandria, VA 22314.

DECLARATION OF ORHUN K. MURATOGLU

I, Orhun K. Muratoglu, do hereby declare as follows:

1. I received my Ph.D. in Materials Science and Engineering, Program in Polymer Science and Technology, from the Massachusetts Institute of Technology ("MIT") in 1995. I have been engaged in the study of polymers, such as ultra high molecular weight polyethylene (UHMWPE), for use in medical implants for over 15 years. I have authored or co-authored at least 50 peer-reviewed articles and 14 book chapters and review articles concerning cross-linked and wear resistant UHMWPE and methods of making such UHMWPE for medical implants. I am currently the co-director of the Harris-Orthopedic Laboratory at the Massachusetts General Hospital. A copy of my *curriculum vitae* is attached at tab 1.

2. I have been using the van de Graaff generator at the MIT that was used in the captioned application for over a decade. In the past, I have used the van de Graaff generator that was used to carry out the actual crosslinking of the polymeric materials utilized in the captioned application.

3. I provide this declaration to describe the van de Graaff generator, the process involved cross-linking polymers using the generator and the steps that are inherent in the

process that one skilled in the art would understand.

4. I herewith provide several sketches (see attached Exhibits 1, 2, and 3) of the conveyor method used with the van de Graaff generator for irradiation of polymeric materials with energetic electrons. Because energetic electrons are hazardous, the conveyor-belt irradiation is performed in a well-shielded room designed to prevent hazardous radiation leaving outside the room.

5. Exhibit 1 identifies the conveyor belt that is used to move samples to pass under the e-beam of energetic electrons. Exhibits 2 and 3 show side and front views, respectively. For irradiation by electrons, the samples are carried by the conveyor belt under the constant 'shower' beam of energetic electrons provided by the generator. The amount of total dose desired is used to determine the intensity of the electron beam, and also the number of passes under the beam if more than one passes are required for higher levels of total dose.

For example if a total dose of 25 kGy was to be delivered to a sample, it could be done with a single high intensity pass of 25 kGy/pass, or it might be done with 2 passes of 12.5 kGy/pass, or perhaps with 5 passes of 5 kGy/pass, or 10 passes of 2.5 kGy/pass. For 100 kGy dose one could use 4 passes of 25 kGy/pass. Thus, the total dose is the additive sum of the dose per pass accumulated over the number of passes.

6. Thus, in order to obtain a desired total dose multiple passes may be required, which can be accomplished by reversing the direction of the conveyor, or alternately shutting the machine off going into the irradiation shielded room and physically moving the sample to the starting point again, closing the room, starting the machine and again running the conveyor in the same direction for each pass.

7. In any case, van de Graaff generator involves:

- A conveyor belt.
- Cycles of radiation necessary to obtain a total dose, that is, the e-beam radiation ceases when the specimen is outside the 'shower' beam of energetic electrons generated by the van de Graaff generator. The sample receives no radiation dose when it is outside of the e-beam radiation station and continues to move on the conveyer belt until it is put back on the belt or

the direction of the belt movement is reversed for a second dose. The process is repeated, as discussed above, for example to obtain a total dose of 5 Mrad or more, because the van de Graaff generator provides a dose of 2.5 Mrad per pass in the captioned application. The van de Graaff generator can also be adjusted to deliver higher or lower radiation doses per pass. It should be therefore clear to the skilled persons and lay persons alike from the sketches (see Exhibits 1 and 2) that there is a pause or the radiation ceases when sample passes out of the radiation zone and the steps of radiation and ceasing radiation are repeated.

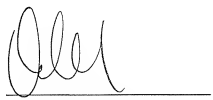
- If the process requires, heating can be continued after each dose of radiation until the desired total dose is received.
- Heating to melt after passages through the conveyor belt also can be done if the radiation is carried out on a heated specimen.
- In any case, the specimens must be taken out of the conveyor belt or out of the radiation "shower" zone and reintroduced to continue on the irradiation process by placing the specimen to the starting point or by reversing the direction of the conveyor belt.
- The irradiation can be performed while the specimen is moving on a belt when multiple doses are necessary to achieve a total absorbed dose (for example 25 MRads).
- If the process requires, the specimen is cooled to room temperature when taken out of the belt or out of the "shower' beam in between the doses.
- If the process requires, the specimens can be taken out of a belt to continue on heating to re-melt when reintroduced to the belt to continue irradiation and heating.

8. As clarified, if a van de Graaff generator is disclosed, one skilled in the art would understand the inherent disclosure of:

- a conveyor belt;
- cycles of radiation;

- ceasing of radiation in between doses until a total desired doses is achieved;
- heating and/or cooling as necessary after passages through a conveyor belt; and
- even if it is not spelled out that the specimens are taken out of the conveyor belt or the electron "shower" beam in between the doses, one skilled in the art would understand that the specimens are taken out of the e-beam "shower" to be reintroduced to continue the irradiation process until the desired radiation dose is attained.

9. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.



March 23, 2011
Date

Orhun K. Muratoglu

Exhibit 1.

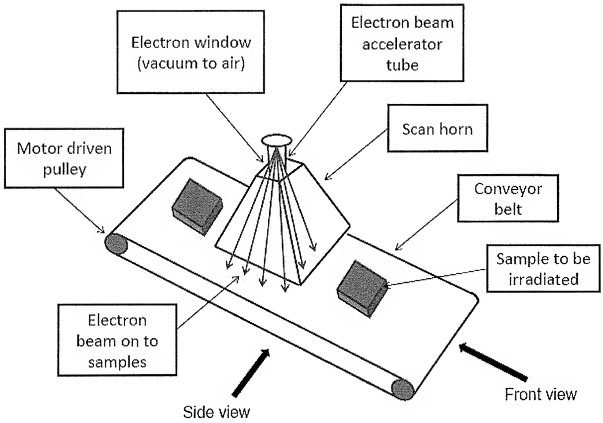
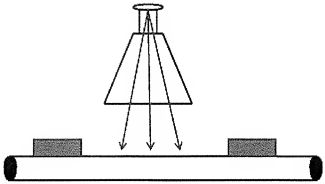
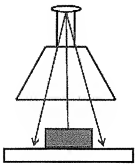

Electron window (vacuum to air)
Electron beam accelerator tube
Scan horn
Motor driven pulley
Conveyor belt
Sample to be irradiated
Electron beam on to samples
Side view
Front view

Exhibit 2.



Side view

Exhibit 3.



Front view